UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,852	12/19/2000	Petrus J.A. Meeuwsen	251502008400	5307

25225 7590 01/06/2006

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,852	MEEUWSEN ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *7-19,22-33 and 35-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,20,21 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/9/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/EP99/00860 filed on 12/19/2000.

The preliminary amendment filed on 7/22/2005 is acknowledged. The newly amended claim 15, original claims 1, 2, 3, 5, 8, 9, 11, 21, 23, 24, 27, previously presented claims 4, 7, 10, 12, 13, 14, 16, 17, 18, 19, 20, 22, 25, 26, 34, 42, 43, 44 and non-elected claims 28, 29, 30, 31, 32, 33, 35, 36, 37, 38, 39, 40, 41 have been entered.

The previous Office Action restricted the claims but there were typographical errors in the groupings of the claims, such as in Group III, claims 22-37 should be 22-27, and claim 27 should be deleted from Group I. Furthermore claims 20-21 and 34 inadvertently left in Group II should be deleted. Therefore, Group I encompasses claims 1-6, 20-21 and 34.

Applicant's election with traverse of Group I, Claims 1-6, 20-21 and 34, drawn to a polypeptide having activity to hydrolyze xylogalacturonic acid polymer or polygalacturonic acid polymer in the response filed on 10/11/2005 is acknowledged.

The traversal is on the ground(s) that there is no lack of unity, however, examiner finds that lack of unity exists because if a product is known then product lacks special technical feature and there is no contribution over the prior art. The invention of the instant application is a polypeptide having xylogalacturonase activity, which hydrolyze galacturonic acid polymer in plant fruit cell wall in endolytic fashion while galacturonan may or may not be substituted with xylose. Therefore, this polypeptide activity mainly is cleaving galacturonic acid polymer at the internal glycosidic bond. The applicant clearly define the endo-xylogalacturonase activity in the specification p3 lines 11 that "endoxylogacturonase activity is defined as the ability to cleave a

galacturonic acid polymer found in pectin which may be at least partially substituted with xylose at internal glycosidic bonds". Furthermore, in p3 lines 23 of the specification, applicants also disclose, "The two galacturonic acid residues between which the polypeptides of the invention cleave may both be (xylose) substituted or only one may be (xylose) substituted or (preferably) neither may be (xylose) substituted". Therefore, this polypeptide is a galacturonase, which cleaves galacturonic acid-galacturonic acid linkage (p3, lines 16 of the specification) in the pectin. Therefore, this enzyme is nothing but a xylogalacturonase or xylogalacturonan hydrolase or polygalacturonase or polygalacturonic acid hydrolase, galacturonase or galacturonan hydrolase or galactanase, which are almost functionally same as the polypeptide, disclose by the applicant. Applicants argue that the reference cited by the examiner in the restriction requirement (WO95/34223 and Renard et al. see IDS) does not teach endo-xylogalacturonase, which is not persuasive. In fact Heldt-Hansen et al. and Renard et al. both disclose the polypeptide having activity (Fig. 3, and p162, line 4 in Renard et al. and in claim 7 of WO95/34223, which cleaves galacturonic acid-galacturonic acid linkage of internal bonds, which means endolytically such as galactanase as well as endo-polygalacturonase. The examiner would like to remind the applicants that "endo" is a functional term of a polypeptide.

"The technical feature linking Groups I-VI appears to be that they all relate to a "polypeptide" having activity of xylogalacturonase or xylogalacturonan hydrolase or polygalacturonase or polygalacturonic acid hydrolase, galacturonase or galacturonan hydrolase or galactanase. However, said technical feature is not a special technical feature, as the polypeptides (functionally) are known in the art. In addition, as restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of

inventions, which are independent or distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-19, 22-33, and 35-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-6, 20-21 and 34 are under consideration and are being examined herein.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

In this case abstract is missing. Appropriate corrections are required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring nucleic acids and /or proteins are considered non-statutory subject matter. *Diamond and Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein". For examination purpose the claim is read as such.

Claim Objections

Claims 3-6 and 21 are objected to because of the recitation "A ---", which refers to a previous claim. "A ---" should be changed to "The ---". Appropriate correction is required.

Claim 4 is objected to because of the recitation "sequence set out in SEQ ID NO: 2", should be sequence of SEQ ID NO: 2". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 4 is indefinite and vague in the recitation of the "substantially homologous" as it is unclear how homologous to SEQ ID NO: 2 a sequence must be to be encompassed by the phrase "substantially homologous".

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 34 is unclear of "An (animal) food or feed" as it is unclear if what is in parenthesis is part of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 20-21 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of protein molecule encoding any polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity or any endo-xylogalacturonase comprising any fragment of SEQ ID NO 2, or any fragment of SEQ ID NO: 2 of at least five amino acid. The specification teaches the structure of only a single representative

species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding any polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity or any endo-xylogalacturonase comprising any fragment of SEQ ID NO 2, or any fragment of SEQ ID NO: 2 of at least five amino acid. While claims 4 and 5 recite some structural features of the claimed xylogalacturonase protein, the recited structural features (i.e. comprising a fragment of SEQ ID NO: 2 or comprising at least five amino acids of SEQ ID NO: 2) do not constitute a substantial portion of the genus as these structural features are insufficient to provide the recited function and the structural feature necessary in all numbers of the genus in order to provide this function are not recited. Given this lack of description of representative species encompassed by the genus of proteins used in the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-5, 20-21 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity of SEQ ID NO: 2or compositions thereof, does not reasonably provide enablement for any xylogalacturonan hydrolase or any xylogalacturonase having 60% identity to an enzyme of SEQ ID NO: 2 or a compositions of such enzymes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-5 20-21 and 34 are so broad as to encompass any polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity or any xylogalacturonase having 60% identity to an enzyme of SEQ ID NO: 2 and compositions thereof. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of only one polypeptide.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of the nucleic acid molecule encoding the polypeptide, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all polypeptides having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity or all

xylogalacturonases with 60% identity to the enzyme of SEQ ID NOS: 2 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity; (B) the general tolerance of the polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity with an enormous number of amino acid modifications of the polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity of SEQ ID NO: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide having endo-xylogalacturonase or endo-xylogalacturonan hydrolase activity having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Renard et al. ("The xylose rich pectins from pea hulls", Int J Biol Macromol. 1997 Aug; 21(1-2): 155-62, see IDS) and Schols et al. (Different populations of pectic hairy regions occur in apple cell walls", Carbohydr Res. 1995 Oct 2; 275(2): 343-60.). Renard et al. teach about pectin, which is a rich source of galacturonic acid, xylose and arabinose. Renard et al. further disclose that xylose rich polysaccharide i.e. xylogalacturonan could be degraded by endo-polygalacturonase. Schols et al. disclose endopolygalacturonase (PG) and pectin esterase (PE) and rhamnogalacturonase (RGase) isolated from fungus and use of the polypeptides in the degradation of pectic hairy regions in apple cell walls.

Conclusion

Status of the claims:

Claims 1-6, 20-21 and 34 are pending.

Claims 1-6, 20-21 and 34 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Iqbal Chowdhury, PhD
Patent Examiner
Art Unit 1652 (Recombinant Enzymes)
US Patent and Trademark Office
Mail Box. 2C70
Ph. (571)-272-8137
Fax. (571)-273-8137
IC

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600